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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,546	02/10/2004	James E. Van Hoeck	4002-3480	6689
52196	7590	06/09/2006		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/775,546	Applicant(s) HOECK ET AL.	
	Examiner DAVID J. ISABELLA	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48, 58 is/are pending in the application.
- 4a) Of the above claim(s) 21-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

***Status of the Claims***

Claims 21-57 remain withdrawn from consideration as being drawn to a non-elected species of the invention. Claims 49-57 have been cancelled without prejudice. Claims 1-20 and 58 are pending for action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

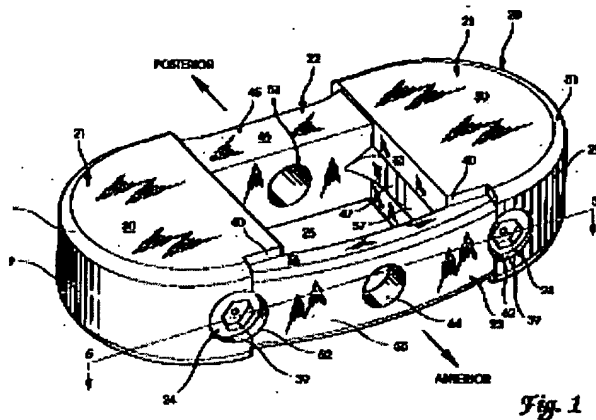
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozak et al (5397364).

Kozak et al discloses, with respect to figure 1, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an anterior wall having a convexly curved anterior surface and opposite ends; a posterior wall having a flat posterior surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face

defining a second opening, said second opening in communication with the chamber.

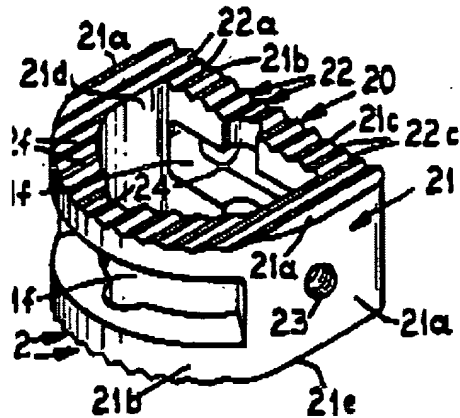


Claims 1 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantigan (5192327)

Brantigan discloses, with respect to figure 2, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an wall having a convexly curved surface and opposite ends; an opposite wall having a flat surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening, said second opening in communication with the chamber. Applicant should note that the structure of the device is identical to that as claimed.

Orientation of the surfaces is determined by the method in which it is deployed in the body.

**FIG. 2**

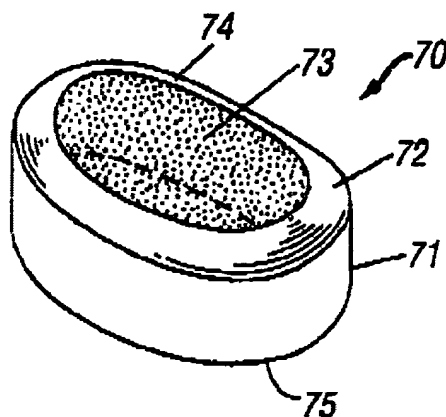


Claims 1-10,12,13,17-18,58 are rejected under 35 U.S.C. 102(b) as being anticipated by Heggeness (5514180).

Heggeness discloses, with respect to figure 4, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an anterior wall having a convexly curved anterior surface and opposite ends; a posterior wall having a flat posterior surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face

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defining a second opening, said second opening in communication with the chamber.



**FIG. 24**

Claims 2-10,12,13,17,18 see columns 10 & 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Silver et al (4703108).

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The use of a matrix, in the form of a sponge, sheet and/or strip, is taught by Silver et al. To form the matrix in the form of a sheet to be inserted in the chamber of Michelson such that the matrix is more easily inserted inside the chamber would have been obvious from the teachings of Silver et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Wozney, et al (5366875).

Wozney et al teaches complexing the BMP with a carrier including polylactic acids and/or collagen for bone repair. To complex the BMP with a carrier to be placed in the chamber of Heggeness so as to provide inductive or conductive new tissue formation into the implant for securing the implant between the adjacent vertebrae would have been obvious from the teachings of Wozney, et al.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Michelson (5609635).

Michelson teaches the use of a threaded opening formed in the implant configured to fit onto a driving end of a insertion instrument to assist in the placement of the implant between the vertebrae. To form a threaded opening in the implant of Heggeness to assist the surgeon in the placement of the implant between the vertebrae

would have been obvious from the teachings of Michelson.

The method of inserting the implant 100 is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening 126 in the trailing end 120 of the implant 100 and the firing of the driving instrument into the depressed portion 124 prevents movement of the implant 100 in relationship to the driving instrument. The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space.

With respect to claim 20, Michelson teaches using roughen external surfaces of the implant to provide for better anchoring/fixation of the implant between the vertebrae.

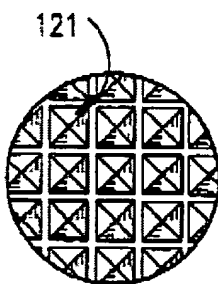


FIG 7

The upper and lower surfaces 112 and 114 of the implant 100 may be flat or curved to conform to the shape of the end plates of the adjacent vertebrae between which the implant 100 is inserted. The implant 100 conforms to the shape of the nucleus pulposus and a portion of the annulus fibrosus removed from the vertebrae. The upper and lower surfaces 112 and 114 comprise surface roughenings that provide a surface suitable for engaging the adjacent vertebrae to stabilize the implant 100 within the disc space once surgically implanted. The surface roughenings of the upper and lower surfaces 112 and 114 comprise a surface knurling 121.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
6/2/2006